K080955

JUN 27 2008

510(K) Summary for the Widex *Zen* Program in the Mind 440 Hearing Aid

Submission Date	**3/ 31/ 2008/; 5/12/ 2008; 6/17/2008**
Applicant	**Widex Hearing Aid Company** **35-53, 24th street** **Long Island City, NY 11106** **Phone: 800-221-0188**
Contact Person	**Francis Kuk, Ph.D.** **2300 Cabot Drive, Suite 415** **Lisle, IL 60532** **630-245-0025** **Email: Fkuk@widexmail.com** **Fkuk@aol.com**
Trade or Proprietary Name	**Zen program (Mind 440 hearing aid)**
Device Common Name/ Classification name	**Hearing Aid, Tinnitus Masker**
Product Code	**ESD, KLW**
Classification of Device	**Class I for hearing aid** **Class II for tinnitus masker**
Establishment Registration Number	**2430101**
Address of Manufacturing Site	**Widex A/S** **Ny Vestergaardsvej 25** **DK-3500 Vaerloese** **Denmark**
Reason for Submission	**New Product**
Marketed Devices with Substantial Equivalence	**K043274 Neuronomics Tinnitus Treatment** **K011366 Siemens Custom TCI-Combi** **K974501 Digital tinnitus masking system**

Compliance with Section 514, Performance Standards Not applicable

Indications for use

The Zen program is intended to provide a relaxing sound background for adults (21 years and older) who desire to listen to such a background in quiet. It may be used as a sound therapy tool in a tinnitus treatment program that is prescribed by a licensed hearing healthcare professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management.

Description of Device

The Zen program is an optional listening program within the Widex Mind 440 digital hearing aid family. It is a tool that generates and delivers a relaxing sound background. It may also be used as a sound source to distract and/or mask tinnitus in tinnitus sufferers. A broadband noise and as many as 4 melodic tone patterns that are generated using fractal mathematics can be selected as Zen programs. The clinician can adjust the characteristics (intensity, pitch and tempo) of each program and the patient can retrieve up to 3 programs with the touch of a program button. The Zen can be used with or without amplification.

Technological comparison to predicate devices

The Zen program digitally generates a broadband noise and melodic tones as a tool to manage tinnitus. This is similar to the principles and tools/stimuli used by these predicate devices - K001366; K043274, K974501. The difference is that the Neuromonics device (K043274) uses pre-recorded music and the Siemens TCI-Combi device (K001366) uses only a broadband noise (i.e., no music) stimulus. The DTMS (K974501) device provides a collection of tinnitus masking sounds which also included computer generated musical tones similar to those generated in the Zen program. Furthermore, the Neuromonics is also a dedicated device (for tinnitus), the Siemens TCI-Combi is a hearing aid plus tinnitus masker, and the DTMS is a 4-CD collection that can be played on any CD player. Hearing aid wearers may reproduce the DTMS sounds on any hearing aids through the use of direct audio input (DAI). In that regard, the treatment of the DTMS sounds is similar to how the Zen sounds are treated in the Mind 440 hearing aid.

A side by side comparison among the Zen and the Neuromonics, the Siemens TCI-Combi, and the DTMS predicate devices is shown in the Table below. This comparison shows that the Zen program has similar effectiveness as the predicate devices.

	Zen in Mind 440 Hearing Aid	Neuromonics Tinnitus Treatment System
Intended Use	A tool for generating and delivery of sound stimuli (broadband noise and musical tones) for a relaxed listening background; may be used in connection with Tinnitus Management programs	A tool for delivery and monitoring audio stimuli (broadband noise and music) required for Neuromonics tinnitus treatment
	Zen alone is intended for use in quiet or during leisure activities; HA+ Zen or HA alone can be used at any time depending on the wearer's needs	Intended for use in quiet or during leisure activities
Indications For Use	Hearing impaired wearers desiring a relaxed listening background; also patients reporting of tinnitus, i.e., hearing aid and tinnitus device	Tinnitus patients with or without a hearing loss, i.e., dedicated tinnitus device
Target Population	Adults (21 yr and older) with tinnitus	Adults with tinnitus
Schedule of Use	May be used as hearing aid alone, hearing aid with Zen, or Zen alone depending on clinician's recommendations and wearer's needs	Only worn for tinnitus rehabilitation on an intended schedule of decreasing use over time
Where Used	May be used anywhere	Intended for in-home use
Physical Descriptions	Within the Mind 440 hearing aid family; takes the form of any hearing aid style, e.g. BTE, ITE, ITC, CIC etc	iPod-like device (4.06" x 2.32" x 0.71") with pre-recorded music delivered through Bose headphones
Mechanism	Uses broadband noise and melodic tones. Manages tinnitus through masking and distraction	Uses broadband noise and music to manage tinnitus through masking and distraction
	a. digital synthesis of sounds (music and noise) using fractal mathematics	*a. pre-recorded relaxing music stored within a memory card*
	b. 4 default melodic tone patterns plus one broadband noise	*b. 4 music passages - two classic, two new age plus a broadband "neural shower" noise*
	c. music does not repeat itself, noise is random	*c. music repeats itself*
	d. generated sounds spectrally shaped by the hearing loss of wearer	*d. music and noise spectrally shaped by hearing loss of wearer*
	e. pitch, tempo and intensity can be adjusted by clinician	*e. music stimuli cannot be changed*
	f. wearer adjusts separate VC to change level of hearing aid and Zen sounds	*f. wearer adjusts VC to change level of music*
	g. level of music and noise typically set at 5 dB above patient's in-situ threshold	*g. level of music is set to "low"*
	h. music provides a relaxing listening background to distract and partially mask tinnitus	*h. music provides a relaxing background for distraction of tinnitus*
	i. a broadband white noise is available for immediate masking	*i. a broad band noise ("neural shower") for immediate masking of tinnitus*
Maximum Output Characteristics	Maximum output depends on hearing aid style and hearing loss of patient, amplified sounds typically set below LDL of patient; Zen program level is also internally monitored	Maximum output fixed at 80 dB SPL
	Output frequency response limited by receiver used, the upper limit is typically between 6500 Hz and 10 KHz depending on hearing aid style	Output frequency response to 12.5 K Hz
Power Source	Uses any 1.4 V hearing aid battery (#13, 312 or 10 zinc air depending on model)	Uses rechargeable lithium polymer battery
Dispensing Professionals	Clinicians who are trained in tinnitus management (when Zen is used for tinnitus relief)	Clinicians who are trained in tinnitus management and Neuromonics device
Associated Training Course	Training on the fitting of the Mind 440 hearing aid is provided; Clinician should be trained on tinnitus management to use Zen for tinnitus relief	Specific training course for clinicians
Quality Assurance Standard	ANSI 3.21-2003 to ensure proper functioning of HA	IEC 60601-1 and 60601-1-2 to meet medical safety standards

	Siemens TCI-Combi	Digital Tinnitus Masking System
Intended Use	A tool for generating and delivery of broadband noise to be used in connection with Tinnitus Management programs	A collection of 4 CDs for delivery of audio stimuli for temporary relief of tinnitus
	Intended for use as hearing aid alone, masker alone or masker+HA in quiet or during leisure activities	Intended to be used in quiet or during leisure activities
Indications For Use	Tinnitus patients with a hearing loss, i.e., hearing aid and tinnitus device	Tinnitus patients with or without a hearing loss
Target Population	Adults or children over 5 years of age with tinnitus	Adults with tinnitus
Schedule of Use	May be worn as hearing aid alone, masker alone, or HA plus masker depending on clinician's recommendations and wearer's needs	May be used any time for tinnitus relief, no specific schedule
Where Used	May be used anywhere	Intended for in-home use
Physical Descriptions	Takes the form of any custom HA (i.e., ITE or ITC)	Any commercial CD player and headphone/ loudspeaker; may be outputted through hearing aids via direct audio input (DAI)
Mechanism	Use broadband noises to manage tinnitus through masking and distraction	Use masking noises and computer generated music to manage tinnitus through masking and relaxation
	a. digitally generated noises	*a. digitally recorded sounds*
	b. broadband noise between 84 and 89 dB SPL (in masker alone mode)	*b. broadband signals - masking noise, music, nature sounds, "alpha rhythm" music at various SPL*
	c. random noise	*c. finite duration of sample, may repeat*
	d. noise is not shaped by hearing loss of wearer	*d. stimuli are not shaped by hearing loss of wearer*
	e. choice of 4 different noises – white, pink, speech and high-frequency	*e. music and noise stimuli cannot be changed*
	f. wearer adjusts VC to change level of HA and masker	*f. wearer adjusts VC of CD player to change level of music or stimuli*
	g. level of noise is set by clinician with patient to just mask the tinnitus	*g. level of sound is adjusted by wearer*
	h. no music is available	*h. alpha rhythm music and nature sounds provide a relaxing listening background during tinnitus masking*
	i. broadband noise is used for immediate and temporary masking of tinnitus	*i. a broadband and frequency specific noises are available for immediate masking*
Maximum Output Characteristics	Maximum output of noise is lower than 89 dB SPL (in masker only), MPO on hearing aid is adjusted by clinician based on patient's discomfort level	Maximum output not controlled by software but by patients
	Output frequency response limited to below 7000 Hz	Output frequency response dependent on headphone and loudspeaker used by the patient
Power Source	Uses any hearing aid battery (#312 or #10 Zinc Air depending on model)	Power supply dependent on the power source of the CD player - line to battery supply
Dispensing Professionals	Clinicians who are trained in tinnitus management	Not specified, commercially available
Associated Training Course	No specific clinical program is required; to be used as a tool in tinnitus management	No specific clinical program is required; to be used as a tool in tinnitus management
Quality Assurance Standard	ANSI 3.21-2003 to ensure proper functioning of HA	Not applicable

Conclusion from preclinical tests and clinical studies

A study on the acceptability of the Zen tones to hearing impaired people showed that the majority of listeners (85%) rated the Zen tones as "somewhat relaxing" or ""very relaxing." No preclinical and clinical testing was conducted on the Zen program re: tinnitus because similar effectiveness has been demonstrated by the predicate devices. The Zen program is expected to be just as effective as the predicate devices while the safety of the hearing aid is unaltered.

Information required under Title 21, Section 874.3400, and not already provided above

Risks to health

There is no more risk to the use of the Zen program than the use of conventional hearing aids and/or tinnitus masker. Appropriate labeling will also be included to ensure proper use of the program.

Hearing Healthcare Professional Diagnosis

The sale and fitting of the Zen program in the mind440 will only be conducted through a Hearing Healthcare Professional, such as an audiologist, hearing aid specialist, or otolaryngologist.

Benefits

The Zen program provides a relaxing listening background for some people. When the Zen program is used in a tinnitus management program, its wearer may experience some relief from tinnitus.

Warnings for safe use

Use of the Zen program may interfere with hearing everyday sounds including speech. It should not be used when hearing such sounds are important. Switch the hearing aid to a non-Zen program in those situations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Widex Hearing Aid Company
c/o Dr. Francis Kuk
Director of Audiology
Suite 415
2300 Cabot Dr.
Lisle, IL 60532

Re: K080955
Trade/Device Name: Zen program
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: March 31, 2008
Received: April 3, 2008

Dear Dr. Kuk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080955

Indications for Use

510(k) Number (if known): K080955

Device Name: Zen program (Mind 440 hearing aid)

Indications for Use:

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Intended Use

The Zen program is intended to be used in quiet where hearing everyday sounds is not critical.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shu Chen Peng

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K080955

Prescription Use X
(Per 21 CFR 801.109)